



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,430	08/22/2001	Mary Faris	511582005000	9082

36327 7590 04/01/2004

AGENSYS C/O MORRISON & FOERSTER LLP
3811 VALLEY CENTRE DRIVE, SUITE 500
SAN DIEGO, CA 92130

EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/935,430	Applicant(s) FARIS ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 1-18, 20 and 25-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19, 21-24 and 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group XIII (claims 19, 21-24 and 67) in the Paper received August 12, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

2. Claims 1-40 are pending.

Claims 19, 21 and 67 have been amended.

Claims 1-18, 20 and 25-66, drawn to non-elected inventions are withdrawn from examination.

Claims 19, 21-24 and 67 are examined on the merits.

Specification

3. The disclosure is objected to because of the following informality: it contains ATCC designations with no corresponding numbers, see page 15, section c. The essential information such be listed. Applicant is requested to review the entire application for such informalities and correction is required.

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on pages 8, 21, 44, 93 and 110 for example. Applicant is required to review the entire application and delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 19, 21-24 and 67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 19, 21, 22 and 23 are broadly drawn to methods of generating and inducing a mammalian immune response directed to 158P1D7 providing a 158P1D7-related protein. The specification has defined 125P5C8-related proteins, as well as what is considered to be the wild-type counterpart, 158P1D7, see page 14. The definition provided encompasses allelic variants, conservative substitution variants, analogs, homologs and fusion proteins that combine parts of different 158P1D7 proteins or fragments thereof. The written description in this instant case only sets forth the 158P1D7 nucleic acid and polypeptide designated as SEQ ID NO: 656 and 657, respectively. The written description is not commensurate in scope with the claims that embody 158P1D7 and 158P1D7-related polypeptides.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the “written description” inquiry, *whatever is now claimed*. (See page 1117). The

specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

With the exception of nucleic acid, SEQ ID NO: 656 and the encoded polypeptide SEQ ID NO:657, the skilled artisan cannot envision the nucleic acid and the detailed structure of the encompassed polypeptides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that “An adequate written description of a DNA...’requires a precise definition, such as by structure, formula, chemical name, or physical properties’, not a mere wish or plan for obtaining the claimed chemical invention”.

At the time the application was filed Applicants only had possession of SEQ ID NO: 656 and 657 and not nucleotides and polypeptides that share less than 100% sequence identity with SEQ ID NO:2. The specification does not evidence the possession of all the possible mutant polypeptides that could be capable exhibiting the alleged wild type 125P5C8 properties listed on pages 10-13, such as a diagnostic marker. There is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

The full breadth of the claims do not meet the written description provision of 35 U.S.C. 112, first paragraph.

7. Claims 19, 21-24 and 67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement commensurate with the scope of the claimed invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 19, 21-24 and 67 are broadly drawn to methods of generating and inducing an immune response to a 158P1D7 protein and a exposing step that comprises administering a nucleotide sequence that encodes a portion of the said protein. The specification asserts that SEQ ID NO: 656 and SEQ ID NO: 657 are the novel nucleic acid and amino acid sequences, respectively for 158P1D17. However, the specification has also defined 125P5C8-related proteins, as well as 158P1D7 as

allelic variants, conservative substitution variants, analogs, homologs and fusion proteins that combine parts of different 158P1D7 proteins or fragments thereof, see page 14. The specification asserts that 158P1D7 nucleic acids and polypeptides serve as a useful diagnostic agent and/or therapeutic target for cancers of the tissues listed in five distinct organ systems, see page 6 and Table 1. The specification does not reasonably provide enablement for 158P1D7 or 158P1D7-related proteins. The specification provides prophetic assertions of the use of 158P1D7 molecules, however it is not clear that the said molecules which encompass allelic variants, conservative substitution variants, analogs, homologs, fusion proteins and related proteins are capable of acting in the manner suggested by the specification. The specification does not provide for a method of making 158P1D7 proteins based on fragment polynucleotides and non-coding polynucleotides. The specification suggests that 158P1D7 is SEQ ID NO: 656 (cDNA) and SEQ ID NO: 657 (protein), see page 6. However, the specification also lists 158P1D7 as mutant molecules, see page 14. Nucleic acid and amino acid sequences less than 100% of the nucleic acid and amino acid identified as SEQ ID NO: 656 and SEQ ID NO: 657, respectively may not maintain the activities proposed in the specification. It would seem that specific function(s) would be required to make the encoded protein useful for the applications disclosed in the specification, such as for treating disorders related to prostate, bladder, kidney, breast, lung and colon cancer providing immunogenic or therapeutic compositions and strategies for treating cancers that express 158P1D7, see Table 1 on page 116. . Since the amino acid sequence of a polypeptide determines its structural and functional

properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar activity requires a knowledge of and guidance with regard to which amino acid or acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved and detailed knowledge of the ways in which the protein's structure relates to its function. The specification provides essentially no guidance as to which of the infinite possible choices is likely to be successful. The true fact of the state of the art in peptide chemistry is expressed succinctly in the accompanying Lazar article (Molecular and Cellular Biology 8(3): 1247-1252, March 1988). This article presents data that substantiates the fact that the introduction of mutations in an amino acid sequence will yield products with different biological activity from the wild type protein.

From the discussion above, it is clear that the predictability of changes to the amino acid sequence is practically nil as far as biological activities are concerned. The specification fails to provide sufficient guidance to enable one of ordinary skill in the art to make and use the claimed nucleic acids in a manner reasonably correlated with the broad scope of the claims. Without sufficient guidance, the changes which must be made in the nucleic acid sequence, SEQ ID NO: 656 and amino acid residues of SEQ ID NO: 657, which results in less than 100% sequence identity is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue.

Based on the analysis and the teachings presented above it would require undue experimentation for the skilled artisan to practice this invention because there is no

Art Unit: 1642

support in the specification for the enablement of the broadly claimed invention.

Therefore, in view of the insufficient guidance in the specification, extensive experimentation would be required to enable the claims and to practice the invention as claimed.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 19, 21-24 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The recitations "158P1D7" and "158P1D7-related proteins" in claims 19, 21 and 22 are vague and indefinite. It is not clear what qualities, activities or functions deem a protein as being related to wild-type 158P1D7 proteins. Furthermore, the recitation "158P1D7" appears to be a laboratory designation and the sole means of identifying the molecule. The use of laboratory designations only to identify a particular molecule renders the claims indefinite because various laboratories may use different laboratory designation to define the same product. Applicants may obviate this rejection by including a sequence identifying number.

Moreover, it is not clear if "158P1D7" represents wild-type molecules or variants. Accordingly, the metes and bounds of the term cannot be determined.

b. Claims 19 and 67 are vague and indefinite in the recitation "at least a portion of an 158P1D7-related protein" and "portion", respectively. It is not clear which

amino acid residues constitute the portion and the T cell epitope or a B cell epitope and capable of inducing an immune response. The metes and bounds of the claims cannot be determined.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 19, 21-24 and 67 are rejected under 35 U.S.C. 102(e) as being anticipated by United States Patent Application Publication number 2004/0033504 (effective filing April 27, 2000). United States Patent Application Publication #2004/0033504 discloses sequences 10 and 49, a polynucleotide and polypeptide sequence, respectively, which share at least 98% sequence identity to Applicants' SEQ ID NO: 656 and 657, see attached database sheets; page 10, Table 1; pages 26-28 and 62-64. SEQ ID NO: 656 and 657 are a polynucleotide and polypeptide sequences, respectively identified by Applicants as 158P1D7. The disclosed polynucleotides and polypeptides can be used in vaccines and in "method[s] for inducing an immunological response in a mammal that comprises inoculating the mammal with a polypeptide...adequate to produce antibody and/or T cell immune response, including for example, cytokine-cell producing T cells or cytotoxic T cells [CTL]...", see page 6,

sections 0066, 0067 and 0070; bridging paragraph of columns 1 and 2 on page 6.

Inherently, the CTL have the ability to kill an autologous cell that expresses the disclosed 158P1D7 protein.

12. Claims 19, 21-24 and 67 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 01/81363 (effective filing April 27, 2000). WO document 01/81363 discloses sequences 10 and 49, a polynucleotide and polypeptide sequence, respectively, which share at least 98% sequence identity to Applicants' SEQ ID NO: 656 and 657, see attached database sheets; Sequence listing, pages 6, 7, 33 and 34 of 69. SEQ ID NO: 656 and 657 are a polynucleotide and polypeptide sequences, respectively identified by Applicants as 158P1D7. The disclosed polynucleotides and polypeptides can be used in vaccines and in "method[s] for inducing an immunological response in a mammal that comprises inoculating the mammal with a polypeptide...adequate to produce antibody and/or T cell immune response, including for example, cytokine-cell producing T cells or cytotoxic T cells [CTL]...", see page 13, lines 17-25' bridging paragraph of pages 13 and 14. Inherently, the CTL have the ability to kill an autologous cell that expresses the disclosed 158P1D7 protein.

Fri Mar 19 16:57:03 2004

us-09-935-430-656.rmpb

Db 2461 AAAAAAAAAAGATATTGTAAGTAATTACATGCTGAACCTGACTATTGAA 2520
QY 2528 GTCTGGAGCAGCAAAACATAGATGAGA 2555
Db 2521 GTCTGGAGCAGCAAAACATAGATGAGA 2548

RESULT 8

US-10-258-951-10
Sequence 10, Application US/10258951
Publication No. US20040033504A1
GENERAL INFORMATION:
APPLICANT: Agarwal, Pankaj
APPLICANT: Murdock, Paul R.
APPLICANT: Rizvi, Safia K.
APPLICANT: Smith, Randall F.
APPLICANT: Xiang, Zhaoying
APPLICANT: Kabinick, Karen
APPLICANT: Lai, Ying-Ta
APPLICANT: Xie, Qing
TITLE OF INVENTION: NOVEL COMPOUNDS
FILE REFERENCE: GP50025
CURRENT APPLICATION NUMBER: US/10/258,951
CURRENT FILING DATE: 2002-10-28
PRIOR APPLICATION NUMBER: PCT/US01/13360
PRIOR FILING DATE: 2001-04-26
PRIOR APPLICATION NUMBER: 60/199,963
PRIOR FILING DATE: 2000-04-27
PRIOR APPLICATION NUMBER: 60/203,336
PRIOR FILING DATE: 2000-05-11
PRIOR APPLICATION NUMBER: 60/207,087
PRIOR FILING DATE: 2000-05-25
PRIOR APPLICATION NUMBER: 60/207,546
PRIOR FILING DATE: 2000-05-26
NUMBER OF SEQ ID NOS: 78
SOFTWARE: FastSeq for Windows Version 3.0
SEQ ID NO 10
LENGTH: 2526
TYPE: DNA
ORGANISM: Homo sapiens
US-10-258-951-10

Query Match 98.9%; Score 2526; DB 12; Length 2526;
Best Local Similarity 100.0%; Pred. No. 0;
Matches 2526; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
QY 23 ATGAAGCTGTGATTCATCTCTTTATTCATCTCTCTGCTGATATCTTTACCTCC 82
Db 1 ATGAAGCTGTGATTCATCTCTTTATTCATCTCTCTGCTGATATCTTTACCTCC 60
QY 83 CAATCTCCAGCTCTCATCCAGAGGCTTTGATTCCTTTGGCAATGTGAGAAAA 142
Db 61 CAATCTCCAGCTCTCATCCAGAGGCTTTGATTCCTTTGGCAATGTGAGAAAA 120
QY 143 GATGGCAATGCTAATTAATTTGTAAGCAAAAGATCAAGATGTATCTGAATAGT 202
Db 121 GATGGCAATGCTAATTAATTTGTAAGCAAAAGATCAAGATGTATCTGAATAGT 180
QY 203 GTGGCAACATCAGACCTTTCCAACTAAGCTTATTAATAAGGCTTGAAGAGCTTCCAC 262
Db 181 GTGGCAACATCAGACCTTTCCAACTAAGCTTATTAATAAGGCTTGAAGAGCTTCCAC 240
QY 263 ACAATGACTTTCTGGGCTTACCAATGCTATTTCAATACACCTTGATTTAAATAT 322
Db 241 ACAATGACTTTCTGGGCTTACCAATGCTATTTCAATACACCTTGATTTAAATAT 300
QY 333 GCAATATTGATGATGCTGATTTAATGCGCTTGCGCTCCGGAACAACATTCATATCAAT 382
Db 301 GCAATATTGATGATGCTGATTTAATGCGCTTGCGCTCCGGAACAACATTCATATCAAT 360
QY 383 CACAATCTTTAAGAAATCTTAAAGAGATCTTTCATGAGACTGGAACCTGGAATTC 442
Db 361 CACAATCTTTAAGAAATCTTAAAGAGATCTTTCATGAGACTGGAACCTGGAATTC 420

QY 443 CTGCAAGCAGATTAACAATTTTATCAAGATTTGAACCAAGTCCCTTAGCAAGCTCAAC 502
Db 421 CTGCAAGCAGATTAACAATTTTATCAAGATTTGAACCAAGTCCCTTAGCAAGCTCAAC 480
QY 503 AGACTCAAGTGTATTTAATTAATGAACAATGCTATTTGAGAGTCTTCCGCAACATCTTC 562
Db 481 AGACTCAAGTGTATTTAATTAATGAACAATGCTATTTGAGAGTCTTCCGCAACATCTTC 540
QY 563 CGATTTGCTCTTAACCATGATCTGATGCTGGAATCAATTAACAATGCTCTTAT 622
Db 541 CGATTTGCTCTTAACCATGATCTGATGCTGGAATCAATTAACAATGCTCTTAT 600
QY 623 GTTGATTTCTGCAACACATTTGGCCGAATTTGATCTTCACTGAGAGCAACAATGG 682
Db 601 GTTGATTTCTGCAACACATTTGGCCGAATTTGATCTTCACTGAGAGCAACAATGG 660
QY 683 GCTGCAATTTGATCTTATTTGAGTTAAACCTTGTTGAGAGCAATGCTCCAGCT 742
Db 661 GCTGCAATTTGATCTTATTTGAGTTAAACCTTGTTGAGAGCAATGCTCCAGCT 720
QY 743 ATATTGATGATGTTGCTGCAACAGCCCTCAATTTTAAAGAGATATCTAGTAA 802
Db 721 ATATTGATGATGTTGCTGCAACAGCCCTCAATTTTAAAGAGATATCTAGTAA 780
QY 803 CTAAAGAGAAATCTATTTGCTCTACTCCAGCTGTATGAAGAAATAGAGATCTCTCA 862
Db 781 CTAAAGAGAAATCTATTTGCTCTACTCCAGCTGTATGAAGAAATAGAGATCTCTCA 840
QY 863 GGATCATTTACATCTGGAGCAACATCTTCAATTAATGATAGTGCATGCAATGAAGC 922
Db 841 GGATCATTTACATCTGGAGCAACATCTTCAATTAATGATAGTGCATGCAATGAAGC 900
QY 923 AGCTCAATTTCAAACTAATCCACCAAGCAACAGCTTGTATCTATATTAACAAGCA 982
Db 901 AGCTCAATTTCAAACTAATCCACCAAGCAACAGCTTGTATCTATATTAACAAGCA 960
QY 983 TCCATCAATCTCAGAGACCTTACTGCTATTCCTGTATCTGTAAGCAAGTCTATCCCA 1042
Db 961 TCCATCAATCTCAGAGACCTTACTGCTATTCCTGTATCTGTAAGCAAGTCTATCCCA 1020
QY 1043 TCAGACTCTTAATATATGTCAGAGCGCAATGTAAGCTTATGATCTGAAGCT 1102
Db 1021 TCAGACTCTTAATATATGTCAGAGCGCAATGTAAGCTTATGATCTGAAGCT 1080
QY 1103 CCTCGCAAAATCTAGAAAGCTCATCTAGCGGAAATATTTTCAAGTTATAGAG 1162
Db 1081 CCTCGCAAAATCTAGAAAGCTCATCTAGCGGAAATATTTTCAAGTTATAGAG 1140
QY 1163 TCTGATCTAGTGAATAATTTCACTTTGGAATGCTTCACTTGGGAAACAATGATTTGAA 1222
Db 1141 TCTGATCTAGTGAATAATTTCACTTTGGAATGCTTCACTTGGGAAACAATGATTTGAA 1200
QY 1223 GTTCTTGAAGAGATGCTTTATGACCTTAAGCAATTAACAAGAACTTATCTAATAGT 1282
Db 1201 GTTCTTGAAGAGATGCTTTATGACCTTAAGCAATTAACAAGAACTTATCTAATAGT 1260
QY 1283 AACCACTGACCAATTAAGTAAGAGATGCTTGGTCTCCATTAATCTTGAATCTTA 1342
Db 1261 AACCACTGACCAATTAAGTAAGAGATGCTTGGTCTCCATTAATCTTGAATCTTA 1320
QY 1343 TATCTTGAATTAATGCTATTAAGAAATATCTGCAAGAACTTATTCGAATGCTTAA 1402
Db 1321 TATCTTGAATTAATGCTATTAAGAAATATCTGCAAGAACTTATTCGAATGCTTAA 1380
QY 1403 CTTAAAGTCTGATTTAATTAACACCTCTCCAGATTTTACCAACATATTTTTC 1462
Db 1381 CTTAAAGTCTGATTTAATTAACACCTCTCCAGATTTTACCAACATATTTTTC 1440
QY 1463 GGGGTTCTCTAATGATTAATTTTAAACAACAGTTTACCACTCTCTGATAGT 1522
Db 1441 GGGGTTCTCTAATGATTAATTTTAAACAACAGTTTACCACTCTCTGATAGT 1500

Mar 19 16:57:03 2004

us-09-935-430-656.rnpb

QY	30	GGATTAAAGAAATTGACAAATATAGATAGTGTGACTTTAAAGGCGCTGGCCCTCCGAA	367
Db	301	GGATTAAAGAAATTGACAAATATAGATAGTGTGACTTTAAAGGCGCTGGCCCTCCGAA	360
QY	368	CAACTTCATATCAATCAACAATCTTTAGAAATCTTAAAGAGATACCTTCATGACCTG	427
Db	361	CAACTTCATATCAATCAACAATCTTTAGAAATCTTAAAGAGATACCTTCATGACCTG	420
QY	428	GAAGAACTGGAATCTCGAGACATATAAATTTATCAAGAGATTGAACCAATGGC	487
Db	421	GAAGAACTGGAATCTCGAGACATATAAATTTATCAAGAGATTGAACCAATGGC	480
QY	488	TTTAGAGAGCTGAAGAGACTCAAGTGTAAATTTTAAATGCAATGCTATTGAGACTT	547
Db	481	TTTAGAGAGCTGAAGAGACTCAAGTGTAAATTTTAAATGCAATGCTATTGAGACTT	540
QY	548	CTTCGAAACATCTTCGATTTGTCCTTTAAACCATGATGATCTGTGTGAAATCAATTA	607
Db	541	CTTCGAAACATCTTCGATTTGTCCTTTAAACCATGATGATCTGTGTGAAATCAATTA	603
QY	608	CAAAACATGCTTAATGTGTATTTCTCGACACATATGGCCGAATATGATCTTCAGTG	667
Db	601	CAAAACATGCTTAATGTGTATTTCTCGACACATATGGCCGAATATGATCTTCAGTG	660
QY	668	GAGAGCAACAAATGGGCTCGCAATTGTGACTTTGCAATTAAGAAATTTGTTGGAAC	727
Db	661	GAGAGCAACAAATGGGCTCGCAATTGTGACTTTGCAATTAAGAAATTTGTTGGAAC	720
QY	728	ATGCTTCACAGTCTTAATATGTGATGTGTGTGCAACAGCCCTCATTTTTAAAGGA	787
Db	721	ATGCTTCACAGTCTTAATATGTGATGTGTGTGCAACAGCCCTCATTTTTAAAGGA	780
QY	788	AGTATCTCAGTGTGACTTAAGAAAGAACTATTTGGCCCTATCCACAGATGATGAAGA	847
Db	781	AGTATCTCAGTGTGACTTAAGAAAGAACTATTTGGCCCTATCCACAGATGATGAAGA	840
QY	848	CATGAGAGATCTTCAGAGATCATTAATCTGGCAGCAATCTTCATTAATGATAGTGC	907
Db	841	CATGAGAGATCTTCAGAGATCATTAATCTGGCAGCAATCTTCATTAATGATAGTGC	903
QY	908	ATGTCAACTAGACCAAGTCCTCATTTCTAAAGCTACCAACAAAGCACCAGGTTGATAGCT	967
Db	901	ATGTCAACTAGACCAAGTCCTCATTTCTAAAGCTACCAACAAAGCACCAGGTTGATAGCT	960
QY	968	TATTTTAAAGAGCAATCCACTCAATCTCGAGACCTTATAGCCCTATTCCTGTGAATGCG	1022
Db	961	TATTTTAAAGAGCAATCCACTCAATCTCGAGACCTTATAGCCCTATTCCTGTGAATGCG	1022
QY	1028	AAAGTCTTATCCCATCGAGACTTCTTAATACATTTGTGAGAGGCGCAATTTGAAGCTTA	1087
Db	1021	AAAGTCTTATCCCATCGAGACTTCTTAATACATTTGTGAGAGGCGCAATTTGAAGCTTA	1080
QY	1088	TCAGATCTGAGACCTTCCTCGCAAAATCTTGAAGAAAGCTCATTTGAGGGGAAATATATT	1147
Db	1081	TCAGATCTGAGACCTTCCTCGCAAAATCTTGAAGAAAGCTCATTTGAGGGGAAATATATT	1144
QY	1148	CACAGTTTAAAGAGCTGATCTAGTGAATATTTCACTTTGAAAAGCTGACTTTGGGA	1207
Db	1141	CACAGTTTAAAGAGCTGATCTAGTGAATATTTCACTTTGAAAAGCTGACTTTGGGA	1200
QY	1208	ACCAATGCTATGAAAGTTCTTGAAGAGAGATGCTTTATGAACCTAACGAGATTAACAAA	1267
Db	1201	ACCAATGCTATGAAAGTTCTTGAAGAGAGATGCTTTATGAACCTAACGAGATTAACAAA	1266
QY	1268	CTCTATCTAAATGTAACCACTGACCAAAATTTAATGAAGGCAATGTTCTGTCTCAT	1327
Db	1261	CTCTATCTAAATGTAACCACTGACCAAAATTTAATGAAGGCAATGTTCTGTCTCAT	1326
QY	1328	AATCTTGAATACTTATATCTTGAATACATATGCAATTAAGSAAATATGCGACAGAACTTT	1387
Db	1321	AATCTTGAATACTTATATCTTGAATACATATGCAATTAAGSAAATATGCGACAGAACTTT	1386
QY	1388	AATTCATGCTTAACTTAAAGTCTGTATTTAAATACAAACCTCTCCAGTTTAAACA	1447

13

Fri Mar 19 16:57:03 2004

US-09-935-43

Db	2461	ACAAAAATGATTTTGAACCTTAAGCTAATTACAGCTGACCTGACTATTGGA	2520
Qy	2528	GTCTGAGCAGCAACATGATGAGA	2555
Db	2521	GTCTGAGCAGCAACATGATGAGA	2548

10-656.rng

ABA90335
 ID ABA90335 standard; cDNA; 2526 BP.
 XX
 AC ABA90335;
 XX
 DT 12-FEB-2002 (first entry)
 XX
 DE Human polynucleotide #10.
 XX
 KW Human; nootropic; neuroprotective; anticonvulsant; antidepressant;
 KW neuroleptic; tranquiliser; antiarrhythmic; cardiant; antiasthmatic;
 KW antiinflammatory; antilipaemic; hepatotropic; virucide; antidiabetic;
 KW nephrotropic; anorectic; cytostatic; vaccine; neurological disease;
 KW cardiovascular disease; respiratory disease; liver disease;
 KW renal disease; skeletal muscle disease; gastrointestinal disease;
 KW placental disease; testicular cancer; male fertility; pancreatic disease;
 KW ss.
 XX
 OS Homo sapiens.
 XX
 PN WO200181363-A1.
 XX
 PD 01-NOV-2001.
 XX
 PF 26-APR-2001; 2001WO-US013360.
 XX
 PR 27-APR-2000; 2000US-0199963P.
 PR 11-MAY-2000; 2000US-0203336P.
 PR 25-MAY-2000; 2000US-0207087P.
 PR 26-MAY-2000; 2000US-0207546P.
 XX
 PA (SMIK) SMITHKLINE BEECHAM CORP.
 PA (SMIK) SMITHKLINE BEECHAM PLC.
 XX
 PI Agarwal P, Murdock PR, Rizvi SK, Smith RF, Xiang Z, Kabnick KS;
 PI Lai Y, Xie Q;
 XX
 DR WPI; 2002-041392/05.
 DR P-PSDB; ABB53270.
 XX
 PT Novel polypeptides and polynucleotides useful as a vaccine for preventing
 PT and treating diseases associated the polypeptide, e.g. Alzheimer's
 PT disease, dyslipidemia, obesity, diabetes, infertility, asthma, amnesias.
 XX
 PS Claim 2; Page 50; 116pp; English.
 XX
 CC The invention relates to an isolated polypeptide comprising a 277, 480,
 CC 583, 581, 628, 424, 638, 229, 310, 841, 241, 369, 382, 185, 586, 1026,
 CC 844, 782, 262, 394, 471, 485, 286, 533, 495, 350, 619, 490, 462, 255,
 CC 784, 252, 593, 472, 607, 781, 640, 686 or 154 amino acid sequence as
 CC given in the specification. The polypeptides, modulators of the
 CC polypeptides and antibodies against the polypeptides are useful for
 CC treating diseases such as neurological and psychiatric diseases including
 CC Alzheimer's, parasupranuclear palsy, Huntington's disease, myotonic
 CC dystrophy, anorexia and depression; cardiovascular diseases including
 CC congestive heart failure, Hodgkin's disease and myocardial infarction;
 CC respiratory diseases including asthma, chronic obstructive pulmonary
 CC disease, cystic fibrosis and adult respiratory distress syndrome; liver
 CC diseases including hypercholesterolaemia, cirrhosis, viral and nonviral
 CC hepatitis, Type II diabetes mellitus, and impaired glucose tolerance;
 CC renal disease including renal failure, acute tubular necrosis and
 CC glomerulonephritis; skeletal muscle diseases including Eulenburg's
 CC disease, hypoglycaemia and obesity; gastrointestinal diseases including
 CC myotonia congenita and intestinal obstruction; lymph diseases including
 CC lymphagiectasia; diseases of placenta including choriocarcinoma; diseases
 CC of testes including testicular cancer, male reproductive diseases
 CC including low testosterone and male infertility; and disease of pancreas
 CC including diabetic ketoacidosis, Type 1 and 2 diabetes and obesity. The
 CC present sequence encodes a polypeptide of the invention
 XX
 SQ Sequence 2526 BP; 823 A; 555 C; 448 G; 700 T; 0 U; 0 Other;
 Query Match 98.9%; Score 2526; DB 6; Length 2526;

QY	23	TGAACTGTGGATTCATCTCTTTATTCATCTCTCTGACCTGATACCTTACACTC	82
Db	1	ATGAACTGTGGATTCATCTCTTTATTCATCTCTCTGACCTGATACCTTACACTC	60
QY	83	CAAACTCCAGTCTCTCATCCAGAGGCTTGTGATTCTCTTGCATTGTGAGAAAA	142
Db	61	CAAACTCCAGTCTCTCATCCAGAGGCTTGTGATTCTCTTGCATTGTGAGAAAA	120
QY	143	GATGGCACAATGCTAAATTAATTGTGAAGCAAAAGTATCAAGTGGTATCTGAATAAGT	202
Db	121	GATGGCACAATGCTAAATTAATTGTGAAGCAAAAGTATCAAGTGGTATCTGAATAAGT	180
QY	203	GTGCCACCATCAGACCTTTCCACTAAGCTTATTAATAAGGCTTGAAGAGCTTCCAC	262
Db	181	GTGCCACCATCAGACCTTTCCACTAAGCTTATTAATAAGGCTTGAAGAGCTTCCAC	240
QY	263	ACAATGACCTTTGTGGGCTTACCAATGCAATTTCAATACACCTTGGATTTCACATATT	322
Db	241	ACAATGACCTTTGTGGGCTTACCAATGCAATTTCAATACACCTTGGATTTCACATATT	300
QY	323	GCAATATTGATGATAGTGTGCTTTAATAGGCTTGGCTCCTGTGAACAACTCAATCAAT	382
Db	301	GCAATATTGATGATAGTGTGCTTTAATAGGCTTGGCTCCTGTGAACAACTCAATCAAT	360
QY	383	CACAATCTTTAGAAATCTTAAAGAGATATCTTTCATGAGACTGTGAATACTGGAATTC	442
Db	361	CACAATCTTTAGAAATCTTAAAGAGATCTTTCATGAGACTGTGAATACTGGAATTC	420
QY	443	CTGCAAGAGATPACAAATTTATACAGATGTGAACCAAGTGGCTTTAGCAAGCTCAAC	502
Db	421	CTGCAAGAGATPACAAATTTATACAGATGTGAACCAAGTGGCTTTAGCAAGCTCAAC	480
QY	503	AGACTCAAAAGTATTATTTAAATGACAAATGCTATGTGAGTCTTCTCTCCAAATCTTC	562
Db	481	AGACTCAAAAGTATTATTTAAATGACAAATGCTATGTGAGTCTTCTCTCCAAATCTTC	540
QY	563	CGATTGTTCTCTTAAACCCTCTGATCTTGTGTGAATCAATTAACAAATTTGCTTAT	622
Db	541	CGATTGTTCTCTTAAACCCTCTGATCTTGTGTGAATCAATTAACAAATTTGCTTAT	600
QY	623	GTGGTTTCTTGGAACACATGGCCGAATATTGATCTTCAAGTTGGAGGACAAATAATGG	682
Db	601	GTGGTTTCTTGGAACACATGGCCGAATATTGATCTTCAAGTTGGAGGACAAATAATGG	660
QY	683	GCTCTCAATTTGACTTATTTGCAATTAATAAATTGGTTGAGAACATGCTCCACAGTCT	742
Db	661	GCTCTCAATTTGACTTATTTGCAATTTAAAACTTGGTTGAGAACATGCTCCACAGTCT	720
QY	743	ATAATTGGAGTGTGTCTGGAACAGCCCTCATCTTTTAAGAAGATPACTAGAGA	802
Db	721	ATAATTGGAGTGTGTCTGGAACAGCCCTCATCTTTTAAGAAGATPACTAGAGA	780
QY	803	CTPAAAGAGGAATCTATTGTCCTTCTCCACCAAGTATGAAAGAACATGAGGATCTTTCA	862
Db	781	CTPAAAGAGGAATCTATTGTCCTTCTCCACCAAGTATGAAAGAACATGAGGATCTTTCA	840
QY	863	GGATCAATTACATCTGGACAGCAACATTTCAAPAAATGATAGCGATGTCAACTAGACG	922
Db	841	GGATCAATTACATCTGGACAGCAACATTTCAAPAAATGATAGCGATGTCAACTAGACG	900
QY	923	ACGTCATCTTAAAACTACCAACCAAGGCAAGGCTTGAATCTTATATTCAAAAGCCA	982
Db	901	ACGTCATCTTAAAACTACCAACCAAGGCAAGGCTTGAATCTTATATTCAAAAGCCA	960
QY	983	TCCACTCAACTTCCAGACCTTACTAGCCCTATCTCTGTAATCTGCAAAAGTCTATCCCCA	1042
Db	961	TCCACTCAACTTCCAGACCTTACTAGCCCTATCTCTGTAATCTGCAAAAGTCTATCCCCA	1020
QY	1043	TCCAGCTTCTAATACATTTGTGAGAGGCGCAATTGAAAGCTTATCAGATCTGAGACT	1102

Dd	1021	TCAGGACTTCATATGATGTCAGGAGGCGCAATGGAAGGTTATGACTGTGAGACT	1080
Qy	1103	CCCTCCGAAAATCTTGAAGAGTCAATCTTAGCGGGAAATATTTATCCAGATTTAATGAG	1162
Dd	1081	CTTCGGCAAAATCTGTGAAGAGCTCATTTCTAGGGGAAAATTTATTTACAGTTTAATGAG	1140
Qy	1163	TCGATATCTAGTGAATATTTTCACTTTGGAATATGCTTCACTTGGGAAACATCTGATGAA	1222
Dd	1141	TCGATATCTAGTGAATATTTTCACTTTGGAATATGCTTCACTTGGGAAACATCTGATGAA	1200
Qy	1223	GTTCCTGAGAAGAGATCGTTTATGAACCTTAGAGATTACAAAACCTATCTTAATGGT	1282
Dd	1201	GTTCTTGAAGAAGATCGTTTATGAACCTTAGAGATTACAAAACCTATCTTAATGGT	1260
Qy	1283	AACGACCTGACCAATTAAGTAAGGACATGTTCTTGATCTCATATCTTGAATACTTA	1342
Dd	1261	AACGACCTGACCAATTAAGTAAGGACATGTTCTTGATCTCATATCTTGAATACTTA	1320
Qy	1343	TATCTTGAATACATATGCACTTAAGAAATATCTCCAGAAACCTTTATCCAAATGCTTAA	1402
Dd	1321	TATCTTGAATACATATGCACTTAAGAAATATCTCCAGAAACCTTTATCCAAATGCTTAA	1380
Qy	1403	CTTAAAGTCCGTATTTTAAATTAACAACCTCCCTCAAGTTTACACACATATTTTCA	1462
Dd	1381	CTTAAAGTCCGTATTTTAAATTAACAACCTCCCTCAAGTTTACACACATATTTTCA	1440
Qy	1463	GAGGTCTCTCAACTAAGTAAATCTTAAAAACAACCAAGTTTACCATCTACTGTAACT	1522
Dd	1441	GAGGTCTCTCAACTAAGTAAATCTTAAAAACAACCAAGTTTACCATCTACTGTAACT	1500
Qy	1523	AATATTTTGGATGATCTTGATTTCTAACCCAGATTTGACCTGAGATTAACCCCTGGAG	1582
Dd	1501	AATATTTTGGATGATCTTGATTTCTAACCCAGATTTGACCTGAGATTAACCCCTGGAG	1560
Qy	1583	TGCTCCTGTGACCTGTGTGACTGACAGAAATGATACMAAAGTTAAACAAGAACACAGTG	1642
Dd	1561	TGCTCCTGTGACCTGTGTGACTGACAGAAATGATACMAAAGTTAAACAAGAACACAGTG	1620
Qy	1643	ACAGATGACATCTCTGTGCACTTCCCCCGGGCATTTCCACAAAAGAAATTGAAAGCCCTA	1702
Dd	1621	ACAGATGACATCTCTGTGCACTTCCCCCGGGCATTTCCACAAAAGAAATTGAAAGCCCTA	1680
Qy	1703	AATAGTGAATCTCTGTGACAGGTTTGTAAATTAACCATCTCATGCCACACAGACTAGT	1762
Dd	1681	AATAGTGAATCTCTGTGACAGGTTTGTAAATTAACCATCTCATGCCACACAGACTAGT	1740
Qy	1763	TACCTTATGATCAACCACTCTTGCAACAACAATACGCTGATATATTTTACGATCT	1822
Dd	1741	TACCTTATGATCAACCACTCTTGCAACAACAATACGCTGATATATTTTACGATCT	1800
Qy	1823	CTTAGGGAAGCGTGGSCACATGCTGTTTATATTTGGAACCTTCGATTAATGTTCACT	1882
Dd	1801	CTTAGGGAAGCGTGGSCACATGCTGTTTATATTTGGAACCTTCGATTAATGTTCACT	1860
Qy	1883	ATTGTTTCTGTGCTGACAGGAATAGTGTCTTGTCTTCAACGCAAGAGAAATACAA	1942
Dd	1861	ATTGTTTCTGTGCTGACAGGAATAGTGTCTTGTCTTCAACGCAAGAGAAATACAA	1920
Qy	1943	AAGAAACAGTATGATGAGAAATGAGAAACAACAGTCTGTGACATCTCACTACAGCATG	2002
Dd	1921	AAGAAACAGTATGATGAGAAATGAGAAACAACAGTCTGTGACATCTCACTACAGCATG	1980
Qy	2003	TATGGCATTAACCACTCATCACTAGAAAGACCTTGTGCTCACTCTATGAACAG	2062
Dd	1981	TATGGCATTAACCACTCATCACTAGAAAGACCTTGTGCTCACTCTATGAACAG	2040
Qy	2063	CATATGATGAGGCCATGTTTCAATCTATGAAATGCAATCTTGTGCTCAAGCATCTG	2122
Dd	2041	CATATGATGAGGCCATGTTTCAATCTATGAAATGCAATCTTGTGCTCAAGCATCTG	2100
Qy	2123	GAGAGGAGAGAGAGAGATGAGAAAGAGAGATGATGCAAAACATCTCCAAAGAGT	2182
Dd	2101	GAGAGGAGAGAGAGAGATGAGAAAGAGAGATGATGCAAAACATCTCCAAAGAGT	2160

Fri Mar 19 16:57:02 2004

us-09-935-

Qy 2183 CTTTGGAAACAGGAAAATCATTCACTCACAGGGTCAAATATGAAATACAAAACCACG 2242
|||
Db 2161 CTTTGGAAACAGGAAAATCATTCACTCACAGGGTCAAATATGAAATACAAAACCACG 2220
|||
Qy 2243 AACCAATCAACAGAATTTTATCCTTCCAAGATGCCAGCTCATTGTACAGAAACATTTA 2302
|||
Db 2221 AACCAATCAACAGAATTTTATCCTTCCAAGATGCCAGCTCATTGTACAGAAACATTTA 2280
|||
Qy 2303 GAAAAAGAAAGGGAACCTCAGCAACTGGGAATCACAGAATACCTAAGGAAAAACATTGCT 2362
|||
Db 2281 GAAAAAGAAAGGGAACCTCAGCAACTGGGAATCACAGAATACCTAAGGAAAAACATTGCT 2340
|||
Qy 2363 CAGCTCCAGCCTGATATGGAGGCACATTATCCTGGAGCCCACGAAGAGCTGAAGTTAATG 2422
|||
Db 2341 CAGCTCCAGCCTGATATGGAGGCACATTATCCTGGAGCCCACGAAGAGCTGAAGTTAATG 2400
|||
Qy 2423 GAAACATTAATGTACTCAGTCCAAGGAAGGTATTAGTGGAAACAGACAAAAATGAGTAT 2482
|||
Db 2401 GAAACATTAATGTACTCAGTCCAAGGAAGGTATTAGTGGAAACAGACAAAAATGAGTAT 2460
|||
Qy 2483 TTTGAACTTAAAGCTAATTTACATGCTGAACCTGACTATTTAGAAGTCTGGAGCAGCAA 2542
|||
Db 2461 TTTGAACTTAAAGCTAATTTACATGCTGAACCTGACTATTTAGAAGTCTGGAGCAGCAA 2520
|||
Qy 2543 ACATAG 2548
|||
Db 2521 ACATAG 2526

Art Unit: 1642

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule and normally can be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne "Bonnie" Eyler, Ph.D. can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER



Alana M. Harris, Ph.D.
March 22, 2004